



## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

JAN  
16  
1996

Applicant: Kohno, et al.

Serial No.: 08/259,413

Filed: June 14, 1994

For: PEGYLATION REAGENTS  
AND COMPOUNDS FORMED  
THEREWITH

Group Art Unit:

Examiner:

Honorable Commissioner of  
Patents and Trademarks  
Washington, D.C. 20231

DECLARATION UNDER 37 CFR SECTION 1.47(a)

Dear Sir:

I, Theresa A. Brown, Esq., hereby declare that:

1. I am Senior Patent Attorney at Synergen, Inc. ("Synergen") of Boulder, Colorado and have been employed in that capacity since October 1992. I am personally familiar with the matters set forth in this Declaration.
2. David Kachensky and Hiko Kohno (the "Executing Joint Inventors") are employed as scientists by Synergen and were so employed during all time periods relevant to this Declaration. Employee agreements between Synergen and the Executing Joint Inventors require the Executing Joint Inventors to assign their inventions to Synergen.

## CERTIFICATE OF MAILING BY "EXPRESS MAIL"

EXPRESS MAIL MAILING LABEL NUMBER EF6711931474US  
DATE OF DEPOSIT 1-3-95

I HEREBY CERTIFY THAT THIS PAPER OR FEE IS BEING DEPOSITED WITH THE UNITED STATES POSTAL SERVICE EXPRESS MAIL POST OFFICE TO ADDRESSEE SERVICE UNDER 37 CFR 1.10 ON THE DATE INDICATED ABOVE AND IS ADDRESSED TO THE COMMISSIONER OF PATENTS AND TRADEMARKS, WASHINGTON, D.C. 20231.

Theresa A. Brown  
(TYPED OR PRINTED NAME OF PERSON MAILING PAPER OR FEE)  
Theresa A. Brown  
(SIGNATURE OF PERSON MAILING PAPER OR FEE)

3. Dr. Milton Harris, the non-executing joint inventor, is employed by and is President of Shearwater Polymers, Inc. ("Shearwater"), located in Huntsville, Alabama.

4. I participated in the drafting and am familiar with the License Agreement and the Collaborative Research Agreement entered into between Synergen and Shearwater and fully executed by them on or about June 11, 1993 (collectively the "Synergen/Shearwater Agreement"). A redacted copy of the Synergen/Shearwater Agreement is attached hereto as Exhibit A. The applicants stand prepared to provide any redacted portions of the Synergen/Shearwater Agreement upon the written request of the Patent and Trademark Office.

5. Pursuant to the Synergen/Shearwater Agreement, Synergen agreed to fund certain research to be performed by Shearwater and, in return, obtained among other things certain rights in the results of that research. Among other things, the agreement at section 4.2 grants to Synergen the exclusive, first right to prepare, file, prosecute and maintain patent applications relating to the subject matter of the agreement. Shearwater agreed to assist Synergen in its patent prosecution efforts. (Exhibit A, section 4.2).

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6. The subject matter of the present patent application represents the results of certain research performed under the Synergen/Shearwater Agreement. (Exhibit A of Exhibit A). Pursuant to section 4.2 of the Synergen/Shearwater Agreement, Synergen has the exclusive, first right to file and prosecute the present application.

7. On or about November 12, 1993, Dr. Harris and/or Shearwater filed U.S. Patent Application Serial No. Serial No. 08/151,481 (the "Harris Application").

8. Pursuant to the Synergen/Shearwater Agreement, Synergen prepared a draft of the present patent application. The Application claims priority to, inter alia, the Harris Application.

9. Prior to March 21, 1994, Synergen sent Dr. Harris the draft patent application. On March 21, 1994, Synergen sent revised claims for the draft application to Mr. Paul Pedigo, who is an attorney and represents Dr. Harris and, apparently, Shearwater in certain matters. A copy of the cover letter to Mr. Pedigo is attached hereto as Exhibit B.

10. On or about March 24, Synergen discussed the application with Mr. Pedigo. Mr. Pedigo expressed concern that

the draft application claims subject matter also claimed in the Harris Application.

11. On May 13, 1994, Synergen sent a revised draft application to Mr. Pedigo and Dr. Harris. Synergen requested technical information from Dr. Harris and comments from Mr. Pedigo. A copy of the cover letter sent to Mr. Pedigo is attached hereto as Exhibit C. An unsigned copy of the cover letter sent to Dr. Harris is attached hereto as Exhibit D. In fact, Dr. Harris provided technical input and comments regarding the present application to Nancy DeSantis, who was working under my supervision.

12. On June 9, 1994, Dr. Harris sent Synergen a facsimile stating he understood that Synergen would be filing the present application on June 13, 1994, and that he would receive a copy of the application as filed along with certain documents for his review. Although Dr. Harris understood Synergen intended to file the present application on June 13, Dr. Harris neither refused to execute a declaration nor requested that Synergen not file the present application. In fact, he stated he wanted Mr. Pedigo to review the present application before he "sign[s] off." A copy of the facsimile is attached hereto as Exhibit E.

13. On June 14, 1994, Synergen elected to protect its interests by timely filing the present application pursuant to 37 CFR § 1.53 and 37 CFR § 1.41. The present application is in all relevant respects substantially the same application Dr. Harris had previously reviewed. As of June 14, 1994, Dr. Harris had not refused to execute a declaration and had not requested that Synergen refrain from filing the present application.

14. Section 1.41(c) states, in relevant part, that "[a]ny person authorized by the applicant may file an application for patent on behalf of the inventor or inventors . . . ." Synergen was authorized to file the present application in the name of Dr. Harris under the Synergen/Shearwater Agreement as discussed above. Synergen was authorized to file the application in the name of the Executing Joint Inventors pursuant to the employee agreements also mentioned previously.

15. On or about June 17, 1994, Synergen sent the Application with an Oath and Declaration to Dr. Harris for his signature. A copy of the cover letter to Dr. Harris is attached hereto as Exhibit F.

16. The Patent and Trademark Office mailed a Notice to File Missing Parts regarding the Application on August 2, 1994. Synergen received the Notice on August 5, 1994.

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17. On or about August 23, 1994, Synergen informed Dr. Harris of the Notice and provided Dr. Harris with a revised Declaration indicating the serial number and filing date of the application. A copy of the cover letter is attached hereto as Exhibit G.

18. On or about September 23, 1994, Mr. Pedigo informed Synergen by letter that he had received a copy of the August 23, 1994, correspondence with Dr. Harris. In addition, the letter stated:

Please be assured that we are committed to working with Synergen and have every desire to cooperate with Synergen for the mutual benefit of both parties and either Synergen or Shearwater.

As we have discussed in the past, Dr. Harris and we at the firm have some concerns about the proposed CIP application. One such concern is that the proposed CIP claims inventions that are claimed in previously-filed applications of different inventive entities; and these applications are not commonly owned. Priority claims based upon these previously-filed and separately owned applications do not overcome conflicts where the same invention is being claimed.

In our opinion, the claims in the CIP should be limited solely to joint inventions of Dr. Harris and Synergen inventors. Sole inventions now claimed in previously-filed applications should be claimed in separate applications. Claims of the joint inventive entity should be patentably distinct from the subject matter disclosed in Synergen's and Shearwater's previously-filed and separately owned applications. The previous separately owned applications of Synergen and Shearwater and Synergen's PCT International Application, PCT/U.S. 92/02122, which was published on October 1, 1992, which is more than one year before the filing date of June 16, 1994 of the proposed CIP, are all prior art documents to be applied against any joint claims for whatever the documents disclose.

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A copy of the letter from Mr. Pedigo is attached hereto as Exhibit H. As this letter shows, as of September 23, 1994, Dr. Harris still had not refused to execute the declaration for the present patent application.

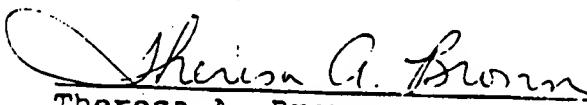
19. In fact, it was not until on or about December 20, 1994, that Dr. Harris informed Synergen, during a telephone conversation with me, that he finally refused to sign the Declaration. Dr. Harris stated his refusal was based on the advice of his attorney, Mr. Pedigo.

20. The last known address of Dr. Milton Harris is: 3119 Highland Plaza, Huntsville, Alabama 35801. This is the same address listed in the Application when filed. Another address at which Dr. Harris can be reached is: c/o Shearwater Polymers, Inc., 2130 Memorial Parkway S.W., Huntsville, Alabama 35801.

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21. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine, imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of this application or any patent issued hereon.

1-3-95  
Date

  
Theresa A. Brown

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